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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vladimir SABETSKY  
Title: ORAL INSULIN COMPOSITION AND METHODS OF MAKING AND USING THEREOF  
Appl. No.: 10/792,376  
Filing Date: 03/04/2004  
Examiner: Unassigned  
Art Unit: 1614

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in

37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search reports.

### **RELEVANCE OF EACH DOCUMENT**

The documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the counterpart international application PCT/IB2004/000933 and related international applications PCT/IB2004/000984 and PCT/IB2004/00961 as well as the counterpart European application 04251253.3 and related European application 04251251.7. Copies of the documents are being provided. A copy of each International Search Report and each European Search Report setting forth the portion of each reference considered relevant by the examiner are attached. References listed on the attached search reports which are not listed on the immediate PTO/SB/08 were previously cited by Applicant in the Information Disclosure Statement filed on April 21, 2004.

Reference B9 is an English language reference which is listed in the International Search Report of international application PCT/IB2004/00961 as being in the same patent family as the French language reference B6 (WO 02/28374). Reference B3 is listed in the European Search Report of European application 04251251.7 as being in the same patent family as references A3 and A4 provided in the previous Information Disclosure Statement filed on 4/21/04.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

8/20/04

By



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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	10/792,376	
Sheet		1	of	1	Filing Date	03/04/2004
					First Named Inventor	Vladimir SABETSKY
					Group Art Unit	Unassigned
					Examiner Name	Unassigned
					Attorney Docket Number	028093-0113

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	B1	4,963,526	A	ECANOW	10-16-1990	
	B2	5,849,884	A	WOISZWILLO, BROWN et al.	12-15-1998	
	B9	2004/0048782	A1	BRYSON	3-11-04	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B3	EP	1 371 364	A	OCTOPLUS B.V.	12-17-2003		
	B4	WO	87/02704	A	ROBINSON	05-07-1987		
	B5	WO	99/02107	A	US BIOMATERIALS CORPORATION	01-21-1999		
	B6	WO	02/28374	A1	FLAMEL TECH SA	04-11-2002		
	B7	WO	02/39985	A	BIOGLAN AB	05-23-2002		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	B8	SOON-SHIONG, "Encapsulated islet cell therapy for the treatment of diabetes: Intraperitoneal injection of islets," <u>Journal of Controlled Release</u> , May 1, 1996, pp. 399-407, Vol. 39, No. 2, Elsevier Science Publishers B.V., Amsterdam, NL	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.